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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Richard Kaplan

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EXAMINER

COLQUITT, AARON BRUCE

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/790,885	Applicant(s) KAPLAN ET AL.	
	Examiner AARON B. COLQUITT	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 71 and 72 is/are allowed.
- 6) ☒ Claim(s) 38-43 and 46-70 is/are rejected.
- 7) ☒ Claim(s) 44-45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This action is in response to the amendment filed on October 19, 2007.

The examiner acknowledges the amendment of claims 38-39, 42, 44-46, 48-51, 55 and 63. Claims 71-72 were added. Claims 38-72 are pending in this application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 38-41, 43, 46-54, and 58-69 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5928133 to Halyak (of record).

In Reference To Claim 38

An automated system for facilitating the implementation of behavioral therapy that uses information indicative of a subject's wake/sleep state to improve the subject's sleep or sleep hygiene, including subjects with insomnia or other sleep complaints, comprising:

passive wake/sleep determination means for producing information indicative of the subject's wake/sleep state (column 2, lines 49-58) and means for implementing the steps of the behavioral therapy utilizing the wake/sleep information (column 4, lines 11-24).

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In Reference To Claims 39-41, 43, 46

Halyak teaches of a combination of therapies in column 2, line 59 to column 3, line 3, wherein information of the stimulus and restriction/relaxation are used. This system also uses EEG's, heart rate, movement sensors, galvanic skin response, and other parameters for sleep research (column 3, lines 58-67), where the user can calibrate the values that are most efficacious for the user (column 5, lines 10-15).

In Reference To Claim 47

An apparatus for facilitating the implementation of behavioral therapy for a subject seeking to improve the subject's sleep or sleep hygiene, including subjects with insomnia or other sleep complaints, comprising:
means for processing information taken from the group consisting of: EEG, EKG, EMG, EOG, actigraphy, body movement, galvanic skin response, respiratory changes, eye movements and combinations of two or more thereof to determine the subject's wake/sleep state; and means for implementing the behavioral therapy utilizing the wake/sleep state information (column 3, line 58 to column 4, line 55).

In Reference To Claims 48-54, 58-69

Halyak teaches that the use of an apparatus that can record varying resistance values can determine when a user should be woken up and that time can be calibrated (column 4, lines 38-42 and column 3, lines 27-33) to the user's needs (column 5, lines 1-15) over a length of time (column 4, lines 10-13) that can be

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viewed on a monitor or printed for a record of the sleep session (column 4, lines 11-24). The apparatus is capable of being worn by the user (column 4, lines 5-10) and can wake the user with an alarm (column 5, lines 20-23) that alerts the user either after the sleep period has been completed (column 5, lines 16-34) or as a failsafe.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 55-57 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halyak in view of US 6392962 to Wyatt (of record).

In Reference To Claims 55-57, and 70

Halyak meets the limitations of the dependent claim but fails to mention whether the subject is in bed or not.

Wyatt, however, teaches of a sleep disorder treatment involving a timer that can be attached to an insomniac's bed, etc (column 6, lines 5-10). The touch pad (24) engages the time to be measured when connected and stops when the pads are disconnected (column 6, lines 43-52). The timer located on the bed can either record time when the pads are connected or disconnected (column 6, line 53 to column 7, line 9) and thus can acquire wake/wake information and can determine if the subject is in bed and display it on either a monitor or printer.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have an automated behavioral therapy system similar to that of Halyak with pads, similar to those of Wyatt, that when separated measure when someone is away from their bed to provide for a sleep therapy that can identify when the subject is in bed to get more informed data on the sleep cycle of the patient.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Halyak in view of US 5573013 to Conlan (Conlan).

In Reference To Claim 42

Halyak meets the limitations of the dependent claims but fails to mention the use of drug therapy in addition to the dependent treatments.

Conlan, however, teaches (column 1, lines 26-36) that by observing body movement information useful to physicians and researchers can be found. for example, by observing a subject's movements, the occurrence and length of natural phenomenon, such as wakefulness, rest and sleep can be determined. By observing the nature of a subject's movement, the occurrence and severity of disorders and the effects of drugs can other therapy can be accessed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have an automated behavioral therapy system similar to that of Halyak with a system that analyzes the effects of drug therapy on sleep

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similar to that of Conlan to provide a therapeutic treatment that uses drug therapy to influence sleep in order to enhance the sleep quality of the patient.

Allowable Subject Matter

6. Claims 71 and 72 are allowable over the prior art of record.

No prior art of record teaches or fairly suggests an apparatus including means for implementing a stimulus control therapy that utilizes sleep/wake information and applies the rules recited in claim 71.

7. Claims 44 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

No prior art of record teaches or fairly suggests an apparatus including means for implementing a stimulus control therapy having the rules recited in claim 44.

Response to Arguments

8. Applicant's arguments see pages 10-11 filed October 19, 2007 regarding claim 38 has been fully considered is not persuasive.

Halyak monitors changes in body resistance (passive) via EEG, heart rate, movement sensors, GSR and other parameters and based off the changes of

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those parameters information of the subject's wake/sleep state is known. When certain known parameters of wake/sleep state are met the user may be gently woken.

Behavioral therapy comprises:

A therapeutic method that focuses on modifying a maladaptive behavior or is a treatment plan designed for a particular person and targets a specific problem or behavior.

The monitor of Halyak is more than just a simple alarm clock. The system assists a person who has a desire to use a bed only for sleeping and not for when they are awake and can change their behavior to suit their needs. When the person is at the stage where they are essentially awake but not quite conscious of it the person awoken at his/her most beneficial time period. The system also takes into account the diet/exercise of the user and the effects it has on their sleep cycle and thus can assist on improving sleep hygiene of the patient.

9. Applicant's arguments see pages 11-14 filed October 19, 2007 regarding claims 39-43 and 46-47 have been fully considered but they are not persuasive.

The primary goal of stimulus control therapy is to have the patient in bed only when drowsy or asleep. This is the same goal of monitoring and awakening device of Halyak.

Stimulus control therapy was developed based on the idea that people with insomnia develop conditioned or learned reactions to their situation, and begins

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to associate the bed and the bedroom with wakefulness rather than sleep. So immediately upon getting into bed, instead of being prepared for wonderful, relaxing, delicious sleep, the person with insomnia becomes hyper-aroused, agitated and experiences yet another night of insomnia, which of course reinforces the problem. So stimulus control tries to break those associations by making sure that the sleeper gets out of bed whenever he or she is awake. The primary recommendation for stimulus control therapy is to stay out of bed whenever you're awake.

The idea behind Halyak is the same as the principles of stimulus control therapy. When a patient is of the proper stage they are advised to get out of bed and thus the bed and the bedroom is associated with sleep rather than wakefulness.

In sleep restriction therapy the primary goal is to have the number of hours that a patient is asleep in bed coincide with the amount of time that the patient is actually in bed and adjustments are made over a period of time to make the time asleep and the time in bed equal. The goal of the monitoring and awakening device is the same as sleep restriction therapy. Since when the patient is essentially awake they exit the bed and begin to associate being awake with not being in the bed.

The apparatus is also able to be programmed to only alert the user during certain hours and may be self set to allow the user to maximize the amount of refreshment and restoration within a short period of time. Therefore each user can have a customized behavioral therapy system based on their wake/sleep information.

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10. Applicant's arguments see pages 14-15 filed October 19, 2007 regarding claims 55-57 and 70 have been fully considered but they are not persuasive.

The apparatus of Wyatt determines wake/sleep states whereby the patient either connects or disconnects pads located somewhere on the surface of the body.

Claim 55 is dependant upon claim 47. Claim 47 does not claim that the wake/sleep detector is passive. Having a pad attached simultaneously attached to the bed and to the patient via an elastic band or another adhesive would determine when the patient has left the bed when the pads are disconnected.

The teachings of a sleep monitoring and awakening device similar to that of Halyak and a sleep time measurement similar to that of Wyatt used together can determine both the degree of sleepfullness and if the patient is in bed or not.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON B. COLQUITT whose telephone number is (571)270-1991. The examiner can normally be reached on Monday-Friday 7:30 - 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272-4730.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/A. B. C./
Examiner, Art Unit 3735